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PATENT

Attorney Docket No. ANGL-06602

## THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Anthony Toranto *et al.*  
Serial No.: 09/976,872  
Filed: 10/12/01  
Entitled: Analyte Detection

Group No.: 1641  
Examiner: D.A. Davis

**TRANSMITTAL OF APPELLANT'S REPLY BRIEF  
TO EXAMINER'S ANSWER  
(PATENT APPLICATION - 37 CFR § 192)**

Mail Stop Appeal Brief - Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

## CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.10

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Dated: April 8, 2005


By: 

Jennifer B. Xistris

Sir or Madam:

Transmitted herewith, in triplicate, is the Appellant's Reply Brief in response to the Examiner's Answer mailed 02/08/2005. It is not believed that any fees are necessary for this reply. However, if any fees are necessary, the Examiner is hereby authorized to charge Deposit Account No. 08-1290 the fee associated with this Reply Brief and any other fees associated with this communication.

Dated: April 8, 2005



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Toranto *et al.*  
Serial No.: 09/976,872  
Filed: 10/12/2001  
Entitled: ANALYTE DETECTION

Group No.: 1641  
Examiner: D. A. Davis

**APPELLANT'S REPLY BRIEF TO EXAMINER'S ANSWER**

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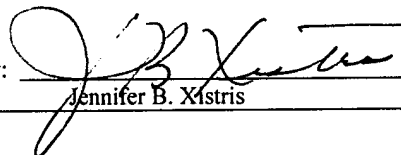
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Date:

4/08/2005

By:

  
Jennifer B. Xistris

Sir/Madam:

This Reply is responsive to the Examiner's Answer (mailed February 8, 2005) to Appellant's Appeal Brief filed September 24, 2004. Appellant believes that the present Reply clearly demonstrates a failure of the Examiner to provide evidence in support of the pending rejection in the original prosecution. The Examiner has provided some evidence (although insufficient), for the first time, in the Examiner's Answer. This is procedurally improper and prevents Applicant from having a proper opportunity to rebut or respond. The Examiner should make such arguments and provide such evidence in a non-final office action. Indeed, this should have been done originally and/or upon Applicant's continued insistence that an evidentiary basis

be provided for the pending rejections. An Examiner's Answer cannot be the point in time where the Office introduces its first evidence to support a rejection.

**The Examiner's Answer provides the first evidence in the record allegedly in support of the Examiner's rejection**

Throughout the original prosecution, the Examiner's rejection was based solely upon the unsubstantiated *assumption* that any chromogen taught for use in an orally administered test must be non-toxic. The Examiner made the following assertions:

The reference of Manautou et al utilizes an oral test strip to test for pregnancy and the chromogen, p-nitrophenol is *apparently* in small enough amounts to be *assumed* safe and non-toxic... It would be *assumed* the [sic] instant reference of Manautou et al would encompass these known safety features, especially when patient [sic] is undergoing oral testing for detection of an analyte wherein said oral test strip utilizes a chromogen, one [sic] skilled in the art would *assume* that a chromogen that is non-irritating and non-toxic [sic].

November 28, 2003 Final Office Action at 6 (*emphasis added*).

Applicant pointed out that this statement lacked evidentiary foundation and that the statement was akin to asserting that any product sold or described for human use at any time in history (the Appellant notes that Manautou *et al.* is over thirty years old) can safely be assumed to be non-hazardous, based on the assumption that no merchant would ever offer unsafe products for sale to the public, or even more tenuously, prophetically describe the use of an unsafe product in a patent. Thus, the rejection was not supported by evidence—but by improper and unsupportable assumption. This alone was sufficient reason to have the rejection withdrawn. However, Applicant further provided evidence in the form of toxicity data obtained by third party investigators indicating that the chromogen of the cited art was lethal at very low doses.

Applicant's arguments and evidence went unrebutted during the prosecution on the merits. The only response by the Examiner was the reassertion of the unsupported assumptions quoted above.

Now, for the first time, the Examiner responds to the Applicant's argument and evidence with specific allegedly contrary evidence. In particular, the Examiner has finally addressed the Applicant's toxicity data by: 1) pointing to a portion of the Manutou reference never before addressed; and 2) carrying out personal calculations using an uncited method to suggest that the amount of chromogen used by Manutou is not at the lethal levels described in the toxicity data. This then leads the Examiner to the conclusion (based again on unsupported standards) that the prior art chromogen is not toxic.

The prior art of Manutou et al teaches that 0.1 to 0.5 ml of a non-toxic buffered substrate consisting of 0.1 M p-nitrophenyl-n acetyl-B-d-glucosaminide (p-nitrophenol) was impregnated on a test strip and placed on a patient's tongue for pregnancy testing (column 3, lines 20-59 and column 4, lines 63-68). The Examiner has calculated and performed conversion factors of 0.1 ml of 0.1 M of p-nitrophenyl-N-acetyl-B-d-glucosaminide to ounces that resulted in 0.000245 ounces. Therefore, the p-nitro-phenol used in the pregnancy strip taught by Manatou et al is less than the amount confirmed to be toxic (.005 ounces) by the Department of Health and Human Services. In the Examiner's view, 0.000245 ounces of p-nitrophenol chromogen meet the limitation of non-toxic recited in the instant invention, and therefore the above claims are considered anticipated by Manautou et al.

Examiner's Answer, text spanning pages 6-7.

**The Examiner's alleged evidence should have been provided during the prosecution on the merits, not in an Examiner's Answer on Appeal**

The Examiner's alleged evidence, cited above, should have been provided in a non-final office action during the prosecution on the merits. It is improper for the Examiner to make new arguments and base rejections on new evidence for the first time during an appeal (see MPEP

1208.01). The basis for this prohibition is self-evident: Applicant's are precluded by such an action from gathering or providing contrary evidence within a reasonable time period and are precluded from presenting amendments or addressing reasons for patentability that could have readily been made during prosecution on the merits if the Examiner had originally introduced the different basis for the rejection. For example, had the Examiner made the above rejections in a non-final office action, the Applicant could have:

- 1) pointed out that the Examiner's calculation is wrong;
- 2) pointed out that the Examiner must provide support for the calculation;
- 3) pointed out that the Examiner has misquoted or mischaracterized Manitou by stating that Manitou describes "non-toxic" buffered substrate;
- 4) pointed out and provided evidence that a level of chemical, even if not lethal, may still be toxic;
- 5) provided evidence that the Manitou levels of chemical, whether based on the Examiner's incorrect calculation or a correct calculation are within a range expected to be toxic;
- 6) pointed out that "in the Examiner's view" is not a proper evidentiary standard for demonstrating a scientific fact unless based on a publication, an affidavit from the Examiner explaining the Examiner's knowledge as to that fact as one skilled in the art, or some other tangible evidence;
- 7) discussed or relied on elements found in dependent claims as additional bases of patentability—a step that was not relevant based on the evidence in the record during the prosecution on the merits;
- 8) added additional elements or claims as additional bases of patentability—a step that was not relevant based on the evidence in the record during the prosecution on the merits.


Procedurally, Applicant is prevented from doing the above during the course of an Appellate reply.

The proper course of action is for the claims to be passed to allowance or for the Office to issue a new non-final office action whereby the Examiner raises the above arguments and alleged evidence in a context where Applicant is afforded the proper ability to respond.

**Conclusion**

For the foregoing reasons, it is submitted that the Examiner's rejection of Claims 1-15 and 18-27 was erroneous, and reversal of the rejection is respectfully requested. The Appellant requests either that the Board render a decision as to the allowability of the claims, or alternatively, that the application be remanded for reconsideration by the Examiner.

Dated: 4/8/05

By: 

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